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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/056,790	01/23/2002	Mario N. Lioubin	EX02-004C	1603
23500	7590 05/20/2003			
JAN P. BRUNELLE			EXAMINER	
EXELIXIS, INC. 170 HARBOR WAY			YAEN, CHRISTOPHER H	
P.O. BOX 511	WAI			
SOUTH SAN FRANCISCO, CA 94083-0511			ART UNIT	PAPER NUMBER
	•		1642	
	,		DATE MAILED: 05/20/2003	Υ

Please find below and/or attached an Office communication concerning this application or proceeding.

		Application No.	Applicant(s)			
Office Action Summary		10/056,790	LIOUBIN ET AL.			
		Examiner	Art Unit			
		Christopher H Yaen	1642			
	- The MAILING DATE of this communication app		e correspondence address			
	Period for Reply					
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).						
Status						
1)⊠	Responsive to communication(s) filed on 23 J	-				
2a)☐	,—	s action is non-final.				
3)∐	3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.					
Disposition of Claims						
4) Claim(s) 1-51 is/are pending in the application.						
4a) Of the above claim(s) is/are withdrawn from consideration.						
5) Claim(s) is/are allowed.						
6)□	Claim(s) is/are rejected.					
7)	Claim(s) is/are objected to.					
	Claim(s) <u>1-51</u> are subject to restriction and/or e	lection requirement.				
Application Papers						
9)☐ The specification is objected to by the Examiner.						
10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner.						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
11)☐ The proposed drawing correction filed on is: a)☐ approved b)☐ disapproved by the Examiner.						
If approved, corrected drawings are required in reply to this Office action.						
12) The oath or declaration is objected to by the Examiner.						
Priority under 35 U.S.C. §§ 119 and 120						
13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).						
•	All b) Some * c) None of:					
1. Certified copies of the priority documents have been received.						
2. Certified copies of the priority documents have been received in Application No						
<ul> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>						
14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).						
<ul> <li>a) ☐ The translation of the foreign language provisional application has been received.</li> <li>15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.</li> </ul>						
Attachment(s)						
2) Notice	of References Cited (PTO-892) of Draftsperson's Patent Drawing Review (PTO-948) ation Disclosure Statement(s) (PTO-1449) Paper No(s)	5) Notice of Inform	nary (PTO-413) Paper No(s) nal Patent Application (PTO-152)			

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## **DETAILED ACTION**

## Election/Restrictions

- 1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-7, drawn to a method of inhibiting growth of tumor cells by administering an antibody, classified in class 424, subclass 178.1.
  - II. Claims 8-12, drawn to a method of screening agents, classified in class435, subclass 5.
  - III. Claims 13, drawn to a method of diagnosing a tumor cell by measuring the RRP expression, classified in class 436, subclass 64.
  - IV. Claims 14-25 and 29-32, drawn to a method of identifying a p53 or p21 modulating agent, classified in class 435, subclass 7.1.
  - V. Claims 26-28, drawn to a method of modulating a p53 or p21 cell wherein the modulator binds to a RRP polypeptide and function is restored, classified in class 436, subclass 500. If applicant elects this group for prosecution on the merits, applicant must also select <u>one</u> sequence from the following sequences: SEQ ID No: 2,4,6,8,10,12,14,16, or 46. This requirement is not to be construed as a requirement for an election of species, since each of the sequence(s) recited in alternative form is not a member of a single genus of invention, but constitutes an <u>independent</u> and patentably distinct invention.

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VI. Claims 33-35, drawn to a method of modulating a p53 or p21 cell wherein the modulator bind to a RRP polypeptide or nucleic acid, classified in class 514, subclass 44.

- VII. Claims 36-38, drawn to a method of diagnosing a disease, classified in class 435, subclass 5.
- VIII. Claims 39-45, drawn to a nucleic acid, host cell and expression system, classified in class 536, subclass 23.1.
- IX. Claims 46-49, drawn to a transgenic mouse, classified in class 800, subclass 8.
- X. Claim 50, drawn to a method of selecting an agent, classified in class 530, subclass 412.
- XI. Claim 51, drawn to a method of making an antibody, classified in class 435, subclass 69.1.

The inventions are distinct, each from the other because of the following reasons:

- 2. Inventions of group I-VII and X-XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions differ one from the other in methodological steps, purpose of use, and desired outcome.
- 3. Inventions VIII-IX and I-VII, X-XI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially

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different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the products of the different groups can be used for materially different methods such as in expression systems.

- 4. Because these inventions are distinct for the reasons given above and the search required for the different groups are not required one for the other, restriction for examination purposes as indicated is proper.
- 5. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).
- 6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H Yaen whose telephone number is 703-305-3586. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-

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308-4242 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

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Christopher Yaen Art Unit 1642 May 16, 2003

> ANTHONY C. CAPUTA SUPERVISORY PATENT EXAMINER TECHNOLOGY CENTER 1600